K 103600

APR - 8 2011

5 510(k) Summary

5.1 Company and Correspondent Making the Submission:

Date Prepared:	June 16, 2008
Name:	DIGIMED Corporation
Address:	#311, ACE HIGH-END TOWER 3, 371-50 Gasan-Dong, Gumcheon-Gu, Seoul, 153-787, Korea
Tel:	+82-2-2624-1551
Fax:	+82-2-2624-1553
E-mail:	kwon@digimed.co.kr
Contact:	Youngbae Kwon, Managing Director

5.2 US Agent for FDA Contact:

Name:	Kim Antol
Company:	Sigma Digital X-Ray
Address:	1607 Barclay Blvd., Buffalo Grove, IL 60089
Tel:	847-419-0669
Fax:	847-419-0675
Email:	KAntol@sigmadigitalxray.com

5.3 Device Information:

Proprietary-Trade Name:	Portable X-Ray System (Models: BIOX)
Classification Name:	Extraoral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800
Common/Usual Name:	Portable X-Ray System

5.4 Predicate Devices :

Manufacturer:	GENORAY Co., Ltd.
Device:	Portable X-Ray System (Model: PORT-X II)
Classification:	Extraoral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800
510(k) Number:	K063121 (Decision Date: Jan. 11, 2007)

5.5 Indications for Use (Intended Use):

The Portable X-ray System (Model: BIOX) is intended to be used by trained dentists and dental technicians as extra-oral X-ray source for producing diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

5.6 Description of Device

The Portable X-ray System (Model: BIOX) is portable dental X-ray system that operates on 24VDC supplied by a rechargeable Li-Polymer battery pack. The X-ray controls and power source are assembled into a single hand-held enclosure. The package includes battery charger.

The Portable X-ray System generates and controls X-ray in order to diagnose teeth and jaw. It is composed of X-ray generator, controller and beam limiting device. Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates teeth and jaw, and makes X-ray images on a receptor (chemical film or digital sensor).

The Portable X-ray System (Model: BIOX) is a diagnostic x-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral image receptors. Its use is intended for both adult and pediatric subjects. This device includes a high frequency inverter that changes direct current to alternating current, X-ray tube, electrical protective devices, and other elements.

The portable X-ray system (Model: BIOX) provides sharp and clear images and protects patients and dentists from leakage radiation by using a lead protective seal.

5.7 Safety and Effectiveness, Comparison to Predicate Device:

The result of bench testing and clinical evaluation indicates that the subject device is as safe and effective as the predicate devices.

5.8 Safety, EMC and Performance Data:

The portable X-ray system, BIOX, will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32. All required documents and reports will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

EMS testing was conducted by EMC Compliance Co., Ltd. and SGS Testing Korea Co., Ltd. for BIOX in accordance with Standard EN/IEC 60601-1-2. All test results were satisfactory.

5.9 Substantial Equivalence Chart

Company name	GENORAY Co.	DIGIMED Corp.
Model	PORT-X II	BIOX
Intended use	Intended to use by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. It is intended to use for both adult and pediatric subjects.	
510k No	K063121	New
Energy Source	Rechargeable 22.2V DC Lithium polymer battery pack	Rechargeable 24V, DC Lithium polymer battery pack Or DC 24V Power Supply
Source to skin distance	20 Cm	210Cm
Cone diameter	7 Cm	6Cm
Expose time	0.01~2.0 seconds 0.01 increments	0.01-1.6 seconds, 0.01 increments
Time accuracy	±(10% +1ms)	±(10% +1ms)
mA	2mA fixed	3mA fixed
kVp	60kV fixed	60kV fixed
Wave form	Constant Potential(DC)	Constant Potential(DC)
Safety, EMC and performance	IEC 60601-1, IEC 60601-1-2 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32
User Interface	Exposure time: up, down select buttons of parts of teeth, adult and child, film and sensor with display	Exposure time: up, down select buttons of parts of teeth, adult and child, film and sensor with display
Exposure switch	Control panel and remote controller	Control panel and remote controller
Tube head mounting	Yes	Yes

5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided the above comparison table, the DIGIMED Corpor -ation concludes that the portable X-ray System (Model: DIOX-602, PROX) is safe and effective and substantially equivalent to the predicate device as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Digimed Corporation
% Mr. Kim Antol
President
Sigma Digital X-Ray
1607 N. Barclay Ave.
BUFFALO IL 60089

APR - 8 2011

Re: K103600
Trade/Device Name: Portable x-ray system (Models: BIOX)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: March 10, 2011
Received: March 10, 2010

Dear Mr. Antol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103600

Device Name: Portable x-ray system (Models: BIOX)

Indications for Use:

The Portable X-ray System (Model: BIOX) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103600